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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,302	11/21/2005	Stephan Schwers	2002P56022US	6176

28524 7590 11/07/2008

SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
170 WOOD AVENUE SOUTH
ISELIN, NJ 08830

EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
11/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,302	SCHWERS ET AL.	
	Examiner	Art Unit	
	Mary K. Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-92* is/are pending in the application.

4a) Of the above claim(s) *17-62 and 77-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-76 and 88-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-92* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/22/05, 8/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election without traverse of Group V, claims 63-76 and 89-92 in the reply filed on 7/30/08 is acknowledged.

All other claims have been withdrawn.

Priority

This application is the national stage application of PCT/EP03/08298. The PCT claims priority to a provisional application filed 8/9/2002. The copy of the certified copy of the priority document is present in the file. The claims pending before the examiner were not those examined by the International Authority.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 8/04/05 and 8/22/05 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Specification

The amendments to the specification, filed 11/21/05 have been entered. The filings related to the computer readable formats of the sequence listing have been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 63-76 and 89-92 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The rejected claims are drawn to methods of calculating a risk of developing cardiovascular disease by observing various genotypes, and making a calculation.

The statute recites four categories of patent-eligible subject matter: processes, machines, manufactures, and compositions of matter. Applicants' claims are not directed to a machine, manufacture, or composition of matter.

From in re Bilski (2008 Fed Circuit): The Supreme Court has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed

process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.

See Benson, 409 U.S. at 70 ("Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines."); Diehr, 450 U.S. at 192 (holding that use of mathematical formula in process "transforming or reducing an article to a different state or thing" constitutes patent-eligible subject matter); see also Flook, 437 U.S. at 589 n.9 ("An argument can be made [that the Supreme] Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing'"); Cochrane v. Deener, 94 U.S. 780, 788 (1876) ("A process is . . . an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.").

The rejected claims are not tied to any particular machine or apparatus. No specific computers or sequencing apparatus is required to perform the method. The method can be performed by merely gathering the data, and performing the calculations by hand, mentally, or with general purpose calculating devices. The rejected claims do not provide a transformation of matter, as they merely perform calculations on previously gathered data.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63-76 and 89-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods of calculating a single patient's risk of developing CVD. However, the steps of claim 63 do not provide for inputting the actual patient's information into the recited (well known) risk calculation. The claim sets forth N 11-13, which are for a "population of patients" and N21-23, which are for information from a "population of patients known not to be at risk. At no point is a single patient genotype used to calculate individual relative risk.. The specification fails to set forth how the admittedly known generic

relative risk calculation (see specification page 71 lines 16-18) is to be used to calculate individual risk of developing CVD.

Further, the claims do not specify the genotypes to be used that are associated with the claimed disease of CVD. The genotypes listed are generically "genotypes 1-3" of populations known to not have CVD, and populations to be tested. The specific genes that are involved in the genotypes are not set forth, nor are they specifically claimed. Cardiovascular disease is a complex disease which involves many systems of the body and multiple chemical and biochemical pathways. CVD is not a single gene disease, and its multifactorial nature has been under study for many years. (Ross, 1993; Lusis, 2000; PTO-1449) A variety of genetic polymorphisms have been studied for their use in treating or predicting CVD with varying success. (for example, Pedro-Botet, 2000; Basso et al., 2002: PTO-1449) The specification sets forth a variety of genotypes in the tables used in various calculations, but it is not known which should be used in these claims to achieve the stated goal. Limitations from the specification cannot be read into the claims. The lack of the particular genotypes makes the dependent claims 64-76 meaningless, as it is entirely unclear what SNP's are to be modified from C-T, or A-G or any of the other recitations. For example, the recitation of "wherein the SNP is a C to T SNP" lacks any indication of where one is to look for this C-T change. Does any C to T change in the entire genome allow for the assessment of an individual's risk of developing CVD? The recitation in the dependent claims of almost every possible transversion possible in a DNA sequence is an invitation to experiment with the human genome and statistics to identify SNP's involved with CVD. The specification fails to teach how any SNP is to be used in that way. Even when the BaySNP's are identified in the dependent claims, it is not set forth which polymorphisms are associated with which genotypes, and it is not set forth how to use these particular SNP's to identify an individual's risk of developing CVD. One of skill in the art would not have known in which genes or portion of the genome to look for these types of SNPs nor would one of skill in the art know which would be useful in the calculation of individual risks.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 63-76 and 89-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to methods of calculating a single patient's risk of developing CVD. However, the steps of claim 63 do not provide for inputting the actual patient's information into the recited risk calculation. The claim sets forth N 11-13, which are for a "population of patients being tested" and N21-23, which are for information from a "population of patients known not to be at risk". At no point is a single patient genotype used to calculate individual relative risk. It would appear the claim is lacking essential method steps for performing the task set forth in the preamble.

In claims 89-92, the limitations as to the genotyping are unclear. what DNA is being genotyped? The claims from which these depend does not set forth obtaining a sample for genotyping, nor does it disclose any steps of actually identifying any sequences or genotypes. As such, these claims lack basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 63-76 are rejected under 35 U.S.C. 102(b) as being anticipated by WO/0022166 (PTO-1449).

The claims are drawn to methods of assessing risk of developing cardiovascular disease by genotyping at least three positions at a SNP, and calculating their risk. The claims do not specify any particular genes to be genotyped.

WO/0022166 discloses methods of assessing risk of developing heart disease by comparing genotypes of at least three polymorphic positions to test patterns known to either carry or not carry a risk for said disease. The use of at least three polymorphoc positions is set forth on page 12. This document also sets forth the use of "polymorphism patterns" which

comprise several SNP's each of which have several possible alleles. (p18) The document uses "any method known in the art " to develop correlations between genotypes and risk of disease. (p26). This documents sets forth using reference populations of data from "healthy" persons, and those known to have various types of CVD. The SNP's studied and disclosed in this document had a variety of changes, including C-T, A-G, A-C, etc. (Tables). As such, this document anticipates the rejected claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjie Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Mary K Zeman/
Primary Examiner, Art Unit 1631